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March 7, 2006

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Commissioner for Patents PO Box 1450 Alexandria, VA 22313-1450 Art Unit 1614

Mail Stop Amendment

Re:

U.S. Utility Patent Application

Application No. 10/518,618; § 371 Date: December 22, 2004

For: Conjugates Comprising an NSAID and a Sugar and Uses Thereof

Inventors:

Holick et al.

Our Ref:

2317.0430001/RWE

Sir:

Transmitted herewith for appropriate action are the following documents:

- 1. Information Disclosure Statement Filing Under 37 C.F.R. § 1.97(b);
- 2. Information Disclosure Statement Form PTO/SB/08A (2 sheets);
- 3. Information Disclosure Statement Form PTO/SB/08B (1 sheet);
- 4. Copies of eight (8) references (Documents FP1-FP4 and NPL1-NPL4);
- 5. First Supplemental Information Disclosure Statement;
- 6. First Supplemental Information Disclosure Statement Form PTO/SB/08A (2 sheets);
- 7. First Supplemental Information Disclosure Statement Form PTO/SB/08B (1 sheet);
- 8. Copies of six (6) references (Documents NPL5-NPL10); and
- 9. Return postcard.

It is respectfully requested that the attached postcard be stamped with the date of filing of these documents, and that it be returned to our courier. In the event that extensions of time are

Commissioner for Patents March 7, 2006 Page 2

necessary to prevent abandonment of this patent application, then such extensions of time are hereby petitioned.

The U.S. Patent and Trademark Office is hereby authorized to charge any fee deficiency, or credit any overpayment, to our Deposit Account No. 19-0036.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.

Robert W. Esmond Attorney for Applicants Registration No. 32,893

Kobuhw. Somon

RWE/dab 504460_1.DOC Enclosures



In re application of:

Holick et al.

Appl. No.: 10/518,618

§ 371 Date: December 22, 2004

For: Conjugates Comprising an NSAID

and a Sugar and Uses Thereof

Confirmation No.: 8983

Art Unit: 1614

Examiner: Kim, Vickie Y.

Atty. Docket: 2317.0430001/RWE

Information Disclosure Statement Filing Under 37 C.F.R. § 1.97(b)

Mail Stop Amendment

Commissioner for Patents PO Box 1450 Alexandria, VA 22313-1450

Sir:

Listed on accompanying Forms PTO/SB/08A and PTO/SB/08B are documents that may be considered material to the examination of this application, in compliance with the duty of disclosure requirements of 37 C.F.R. §§ 1.56, 1.97 and 1.98. Copies of documents **FP1-FP4** and **NPL1-NPL4** are submitted. However, in accordance with 37 C.F.R. § 1.98(a)(2), no copies of U.S. patents and patent application publications cited on the attached Form PTO/SB/08A are submitted.

Where the publication date of a listed document does not provide a month of publication, the year of publication of the listed document is sufficiently earlier than the effective U.S. filing date and any foreign priority date so that the month of publication is not in issue. Applicants have listed publication dates on the attached IDS Forms based on information presently available to the undersigned. However, the listed publication dates should not be construed as an admission that the information was actually published on the date indicated.

Applicants reserve the right to establish the patentability of the claimed invention over any of the information provided herewith, and/or to prove that this information may not be prior art, and/or to prove that this information may not be enabling for the teachings purportedly offered.

This statement should not be construed as a representation that a search has been made, or that information more material to the examination of the present patent application does not exist. The Examiner is specifically requested not to rely solely on the material submitted herewith.

This Information Disclosure Statement is being filed before the mailing date of a first Office Action on the merits. No statement or fee is required.

It is respectfully requested that the Examiner initial and return copies of the enclosed IDS Forms, and indicate in the official file wrapper of this patent application that the documents have been considered.

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Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.

Robert W. Esmond Attorney for Applicants Registration No. 32,893

Date: 3/7/06

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Substitute for form 1449/PTO

DEMARK	Complete if Known		
UE	Application Number	10/518,618	
SURE	§ 371 Date	December 22, 2004	
CANT	First Named Inventor	Holick, Michael F.	
ry)	Art Unit	1614	
,	Examiner Name	Vickie Y. Kim	

INFORMATION DISCLOS STATEMENT BY APPLIC

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Attorney Docket Number 2317.0430001/RWE Sheet of 2

			U.S. PATENT DO		
Examiner Initials*	Cite No.	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages
initials No.	Number-Kind Code ^{2 (If Known)}		Applicant of Cited Document	or Relevant Figures Appear	
	US1	US 4,599,418	07-08-1986	Irikura et al.	
	US2	US 4,774,230	09-27-1988	Tuttle et al.	
	US3	US 5,051,448	09-24-1991	Shashoua	
	US4	US 5,179,093	01-12-1993	Afonso et al.	
	US5	US 5,412,083	05-02-1995	Giese et al.	
	US6	US 5,436,253	07-25-1995	Rinaldi et al.	
•	US7	US 5,436,325	07-25-1995	Johnson et al.	
	US8	US 5,466,681	11-14-1995	Krivan et al.	
	US9	US 5,508,392	04-16-1996	Holick, M.F.	
	US10	US 5,518,738	05-21-1996	Eickhoff et al.	
	US11	US 5,633,357	05-27-1997	Tius et al.	
	US12	US 5,707,605	01-13-1998	Meade et al.	
	US13	US 6,074,625	06-13-2000	Hawthorne et al.	
	US14	US 6,214,345 B1	04-10-2001	Firestone et al.	
	US15	US 6,277,818 B1	08-21-2001	Mazar et al.	
	US16	US 6,548,484 B1	04-15-2003	Christian, S.T.	
	US17	US 2001/0041676 A1	11-15-2001	Holick et al.	
	US18	US 2002/0002140 A1	01-03-2002	Holick et al.	
	US19	US 2003/0216328 A1	11-20-2003	Holick et al.	
	US20	US 2004/0087559 A1	05-06-2004	Schwartz et al.	-

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Examiner Initials*	Cite No.1	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where	
		Country Code ³ Number ⁴ Kind Code ³ (if known)			Relevant Passages or Relevant Figures Appear	T ₆
	FP1	GB 1,029,222	05-11-1966	Beecham Group Limited		
	FP2	WO 92/18005 A1	10-29-1992	National Institutes of Health		
	FP3	WO 94/14411 A1	07-07-1994	Holick		
	FP4	WO 96/03995 A1	02-15-1996	Holick		

Examiner	Date	
Signature	Considered	
Signature	Considered	

^{*}EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. 'Applicant's unique citation designation number (optional). 'See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. 'Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). 'For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. 'Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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INFORMATION DISCLOSURE	§ 3
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STATEMENT BY APPLICANT

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Sheet

Complete if Known					
Application Number	10/518,618				
§ 371 Date	December 22, 2004				
First Named Inventor	Holick, Michael F.				
Art Unit	1614				
Examiner Name	Vickie Y. Kim				
Attorney Docket Number .	2317.0430001/RWE				

			U.S. PATENT DO	CUMENTS	
Examiner Initials*	Cite No.1	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages
muais	Number-Ki	Number-Kind Code ^{2 (If Known)}	WIWI-DD-1111	Applicant of Cited Document	or Relevant Figures Appear
	US21	US 2005/0107310 A1	05-19-2005	Holick et al.	
	US22	US 2005/0153928 A1	07-14-2005	Holick et al.	
	US23	US 2005/0233949 A1	10-20-2005	Holick et al.	
	US24	US 2005/0255038 A1	11-17-2005	Holick et al.	
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			Foreign Patent Do	CUMENTS		
Examiner Initials*	Cite No. ¹	Foreign Patent Document Country Code ³ Number ⁴ Kind Code ³ (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T ⁶

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Signature	Considered	

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Substitute for form 1449/PTO				Con	Complete if Known		
				Application Number	10/518,618		
INFORMATION DISCLOSURE STATEMENT BY APPLICANT		§ 371 Date	December 22, 2004				
		First Named Inventor	Holick, Michael F.				
	Use as many.			Art Unit	1614		
				Examiner Name	Vickie Y. Kim		
Sheet	1	of	1	Attorney Docket Number	2317.0430001/RWE		

		NON PATENT LITERATURE DOCUMENTS	
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume issue number(s), publisher, city and/or country where published	T²
	NPL1	Ali, S.A., et al., "Improving the Tumor Retention of Radioiodinated Antibody: Aryl Carbohydrate Adducts," Canc. Res. (Suppl.) 50:783S-788S, American Association for Cancer Research (1990)	
	NPL2	Database STN Easy, Accession No. 2001:136552, Haubner et al. (February 2001)	
	NPL3	Murakami, K., et al., "Excretion of New Quinolones and their Glucuronide Conjugates into Human Bile," Drugs 49 (Suppl. 2):331-332, Adis International Limited (1995)	
	NPL4	Strobel, J.L., et al., "125I-Glycoconjugate Labels for Identifying Sites of Protein Catabolism in Vivo: Effect of Structure and Chemistry of Coupling to Protein on Label Entrapment in Cells after Protein Degradation," Arch. Biochem. And Biophys. 240:635-645, Academic Press, Inc. (1985)	

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Examiner	Date	
Signature	Considered	

^{*}EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

Holick et al.

Appl. No.: 10/518,618

§ 371 Date: December 22, 2004

For: Conjugates Comprising an NSAID

and a Sugar and Uses Thereof

Confirmation No.: 8983

Art Unit: 1614

Examiner: Kim, Vickie Y.

Atty. Docket: 2317.0430001/RWE

First Supplemental Information Disclosure Statement

Mail Stop Amendment

Commissioner for Patents PO Box 1450 Alexandria, VA 22313-1450

Sir:

Listed on accompanying IDS Forms are documents that may be considered material to the examination of this application, in compliance with the duty of disclosure requirements of 37 C.F.R. §§ 1.56, 1.97 and 1.98. The numbering on this First Supplemental Information Disclosure Statement is a continuation of the numbering in Applicants' Information Disclosure Statement filed concurrently herewith, in connection with the above-captioned application. Copies of documents **NPL5-NPL10** are submitted. However, in accordance with 37 C.F.R. § 1.98(a)(2), no copies of U.S. patents and patent application publications cited on the attached IDS Forms are submitted.

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Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.

Robert W. Esmond Attorney for Applicants Registration No. 32,893

Date: 3/7/06

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Substitute for form 1449/PTO TRADE Complete if Known Application Number 10/518,618 FIRST SUPPLEMENTAL December 22, 2004 § 371 Date INFORMATION DISCLOSURE First Named Inventor Michael F. Holick STATEMENT BY APPLICANT Art Unit 1614 (Use as many sheets as necessary) **Examiner Name** Kim, Vickie Y. Sheet Attorney Docket Number 2317.0430001/RWE/BSA

			U.S. PATENT DO	CUMENTS	
Examiner Initials*	Cite No.1	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages
	140.	Number-Kind Code ^{2 (If Known)}		Applicant of Cited Document	or Relevant Figures Appear
	US25	4,292,425	09-29-1981	Buckler et al.	
	US26	4,261,974	04-14-1981	Buckler et al.	
	US27	4,595,695	06-17-1986	Ladkani et al.	
	US28	4,751,219	06-14-1988	Kempen, H.J.M.	
	US29	4,855,463	08-08-1989	Barua et al.	
	US30	4,894,476	01-16-1990	Butler et al.	
•	US31	4,897,382	01-30-1990	della Valle et al.	
	US32	4,939,174	07-03-1990	Shashoua, V.E.	
	US33	5,114,976	05-19-1992	Norden, M.J.	
	US34	5,162,573	11-10-1992	Chiesi et al.	
	US35	5,340,803	08-23-1994	Rubin, D.	
	US36	5,440,023	08-08-1995	Cheng et al.	
	US37	5,506,224	04-09-1996	della Valle et al.	
	US38	5,559,235	08-24-1996	Luzzio et al.	
	US39	5,561,119	10-01-1996	Jacquesy et al.	
	US40	5,599,953	02-04-1997	Curley, Jr. et al.	
	US41	5,677,286	10-14-1997	Shull et al.	
	US42	5,679,667	10-21-1997	Della Valle et al.	
	US43	5,707,663	01-13-1998	Ayer et al.	
	US44	5,760,072	06-02-1998	de Bont et al.	

		Fo	REIGN PATENT DO	CUMENTS		
Examiner Initials*	Cite No.1	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where	•
		Country Code ³ Number ⁴ Kind Code ³ (if known)			Relevant Passages or Relevant Figures Appear	T ⁶
	FP5					
	FP6					
	FP7					
	FP8					
	FP9					
	FP10					
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Examiner	Date	•
Signature	Considered	

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Substitute for form 1449/PTO TRACE Complete if Known Application Number 10/518,618 FIRST SUPPLEMENTAL December 22, 2004 § 371 Date INFORMATION DISCLOSURE First Named Inventor Michael F. Holick STATEMENT BY APPLICANT Art Unit 1614 (Use as many sheets as necessary) **Examiner Name** Kim, Vickie Y. Attorney Docket Number 2317.0430001/RWE/BSA Sheet of

			U.S. PATENT DO	CUMENTS		
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	No.	Number-Kind Code ^{2 (If Known)}		Applicant of Cited Document	or Relevant Figures Appea	
	US45	5,808,111	09-15-1998	Curley, Jr., R.W.		
	US46	5,827,819	10-27-1998	Yatvin et al.		
	US47	5,977,326	11-02-1999	Scheinmann et al.		
	US48	5,994,392	11-30-1999	Shashoua, V.E.		
	US49	6,024,977	02-15-2000	Yatvin et al.		
	US50	6,043,367	03-28-2000	Roffler et al.		
	US51	6,107,499	08-22-2000	Shashoua, V.E.		
US52		6,166,089 12-26-2000 Kozak, A.				
	US53	6,167,313	3 12-26-2000 Gray et al.			
	US54	6,207,700 B1	05-27-2001	Kalgutkar et al.		
	US55	6,218,519 B1	04-17-2001	Kenten et al.		
	US56	6,287,598 B1	09-11-2001	Ayer et al.		
	US57	6,313,106 B1	11-06-2001	Kozak, A.		
	US58	6,316,027 B1	11-13-2001	Johnson et al.		
	US59	6,339,060 B1	01-15-2002	Yatvin et al.		
-	US60	7,001,888 B2	02-21-2006	Tidmarsh et al.		
	US61	US 2005/0130908 A1	06-16-2005	Holick et al.		
	US62					
	US63					
	US64					

			FOREIGN PATENT DO	CUMENTS		
Examiner Initials*	Cite No. ¹	Foreign Patent Document Country Code ³ Number ⁴ Kind Code ⁵ (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T⁵
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EIDOT OIDD	r tora	en wite	· A T	Application Number	10/518/618	
FIRST SUPPLEMENTAL				§ 371 Date	December 22, 2004	
INFORMATI				First Named Inventor	Michael F. Holick	
STATEMEN				Art Unit	1614	
(Use as many sheets as necessary)			necessary)	Examiner Name	Kim, Vickie Y.	
Sheet	1	of	1	Attorney Docket Number	2317.0430001/RWE/BSA	

		NON PATENT LITERATURE DOCUMENTS	
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	NPL5	Fernández, C. et al., "Synthesis and biological studies of glycosyl dopamine derivatives as potential antiparkinsonian agents," Carbohydrate Research 327:353-365, Elsevier Science Ltd. (2000)	
	NPL6	Lemberber, L., et al., "Fluoxetine: Clinical Pharmacology and Physiologic Disposition," J. Clin. Psychiatry 46(3):14-19, Physicians Postgraduate Press (March 1985)	
	NPL7	Maryanoff, B.E. et al, "Anticonvulsant O-Alkyl Sulfamates. 2,3,4,5-Bis-O-(1-methylethylidene)-B-D-fructopyranose Sulfamate and Related Compounds," J. Med. Chem. 30:880-887, American Chemical Society (1987)	
	NPL8	Maryanoff, B.E. et al., "Structure-Activity Studies on Anticonvulsant Sugar Sulfamates Related to Topiramate. Enhanced Potency with Cyclic Sulfate Derivatives," J. Med. Chem. 41:1315-1343, American Chemical Society (1998)	
	NPL9	Remington's Pharmaceutical Sciences, Osol, A., et al., eds., 16 th edition, Chapter 36, pp. 677-678, Philadelphia College of Pharmacy and Science (1980)	
	NPL10	Rowley, M. et al., "Effect of Plasma Protein Binding on in Vivo Activity and Brain Penetration of Glycine/NMDA Receptor Antagonists," J. Med. Chem. 40:4053-4068, American Chemical Society (1997)	
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